

REMARKS

The Office Action mailed October 19, 2005, has been received and reviewed. Claims 10, 11, 15 through 18, 21 through 23, 27, 29 through 32, 35 through 38 and 46 through 48 are currently pending in the application. Claims 16 through 18, 21 through 23, 27, 29 through 32, 35 through 38 and 46 through 48 stand rejected. Applicants have amended claims 16-18 and 35, have added claims 49-51, and respectfully request reconsideration of the application as amended herein.

Allowable Subject Matter

Applicants wish to thank the Examiner for the indication of allowable subject matter related to claims 10, 11, and 15.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 4,376,118 to Daher et al. and U.S. Patent No. 5,972,373 to Yajima et al.

Claims 16-18, 21-23, 27, 29-32, 35-38 and 46-48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Daher et al. (U.S. Patent No. 4,376,118) and Yajima et al. (U.S. Patent No. 5,972,373). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The Examiner relies on Daher as teaching a non-aqueous solution of tetracycline that includes N-methyl-2-pyrrolidone, lauryl lactate, antioxidant, polysorbate soubilizer. As

acknowledged by the Examiner, Daher does not teach use of polyvinylpyrrolidone. Yajima is relied upon as teaching a composition that contains tetracycline, glycerol monolaurate or glycerol monostearate, polyninylpyrrolidone, and polysorbate or polyoxytheylene-polyoxypropylene block copolymers. Because Daher and Yajima both contain tetracycline antibiotic, the Examiner relies on *In re Kerkhoven* for the proposition that it is obvious to combine two compositions in order to form a third composition to be used for the same purpose. However, independent claim 16 has been amended to require a stable non-aqueous viscous protein formulation comprising at least one protein, and a non-aqueous single-phase biocompatible viscous vehicle comprising a polymer consisting of polyvinylpyrrolidone, a surfactant consisting of glycerol monolaurate or polysorbate, and a solvent consisting of lauryl lactate. Therefore, there is no motivation to combine the cited references. Additionally, the combined references do not teach all of the elements of claim 16.

Likewise, independent claim 35 requires providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single-phase biocompatible viscous vehicle comprising a polymer consisting of polyvinylpyrrolidone, a surfactant consisting of glycerol monolaurate or polysorbate, and a solvent consisting of lauryl lactate; and administering the stable non-aqueous viscous protein formulation to a subject, wherein the administering is long-term and continuous. Independent claim 29 is drawn to a method for preparing the stable non-aqueous single-phase biocompatible viscous vehicle recited in allowable claims 10, 11, and 15.

In view of the foregoing, Applicants respectfully submit that the obviousness rejections based on Daher in combination with Yajima have been overcome and respectfully request withdrawal of the same.

The nonobviousness of independent claims 16, 29, and 35 precludes a rejection of claim 17, 18, 21-23, 27, 30-32, 36-38, and 46-48 which depend therefrom because a dependent claim is obvious only if the independent claim from which it depends is obvious. See *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988), *see also* MPEP § 2143.03. Therefore, the Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 103(a) obviousness rejection to

the cited dependent claims.

ENTRY OF AMENDMENTS

The amendments to claims 16-18 and 35, and the addition of claims 49-51 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments do not raise new issues or require a further search.

CONCLUSION

Claims 10, 11, 15-18, 21-23, 27, 29-32, 35-38 and 46-48 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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